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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,496	10/15/2004	Roy Christiaan Montijn	101137-55	4628

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EXAMINER	
WOOD, AMANDA P	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,496	MONTIJN ET AL.	
	Examiner	Art Unit	
	Amanda P. Wood	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION-Final Rejection

Applicant's response and amendment filed 26 April 2006 is acknowledged and has been entered. Claims 1-11 have been examined on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 103

Claims 1-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Duncan et al (Letters in Applied Microbiology 2000) in view of Larossa et al (US 6,607,885), and further in view of Bott et al (Water Science and Technology 2001).

A method for determining an environmental condition by measuring a biochemical composition of one or more microorganisms exposed to said environmental condition is claimed.

Duncan et al teach a method of determining whether toxic compounds have perturbed a wastewater treatment process (i.e., an environmental condition) by measuring the amount of a stress protein (i.e., a biochemical composition) expressed by the diverse population of microorganisms in the wastewater treatment process. Furthermore, Duncan et al teach that changes in the environmental condition of the treatment process can be monitored by measuring the changes in the amount of stress protein expressed by these microorganisms (i.e., qualitative or quantitative measuring), and that protein induction patterns, or protein fingerprints (i.e., plurality of different

proteins or biomolecules), in these activated sludge cultures can be determined and used in monitoring the treatment process (see, for example, Abstract and Introduction, pgs 28-29). Duncan et al teach that a diverse population of microorganisms exist in these activated sludge cultures, but in particular, *E. coli*, *Rhodobacter sphaeroides*, *Nitrosomonas europaea*, *Sphingomonas capsulata* and *Pseudomonas putida* were used by Duncan et al. In addition, Duncan et al measured the amount of the general shock protein GroEL that was induced in the cells of these bacteria in response to the contamination of the wastewater treatment process (i.e., a bioconversion process in an aqueous environment) under different environmental conditions. Duncan et al further teach that relative levels of stress proteins in conjunction with their induction patterns will lead to the development of a useful monitoring technology based upon microbial stress response.

Duncan et al do not specifically teach a method wherein the biochemical composition is the transcriptome (i.e., measurement of mRNA levels present in a cell), nor a method wherein the biochemical composition is determined using microarrays.

Larossa et al beneficially teach a method wherein the effect of environmental changes is determined by measuring gene expression levels (i.e., the transcriptome) in bacteria. Larossa et al specifically teach that *E. coli* experiments to define stress-related responses in the past have used mRNA measurements to determine an individual gene's expression profile (see, for example col. 1, lines 30-60 and col. 2, lines 20-65).

In addition, Larossa et al beneficially teach a method wherein a bacterial species is subjected to a gene expression altering condition (i.e., an environmental condition) and a microarray of the bacterial RNA is generated so as to identify the gene expression level and changes in the bacteria. Furthermore, Larossa et al beneficially teach that it is possible to monitor the effect of environmental changes on gene expression by comparing expression levels of genes from bacteria that have not been exposed to stress to those of bacteria that have been exposed to stress.

Bott et al beneficially teach that stress proteins are readily induced in bacteria in response to a broad range of environmental stress conditions, including heat, starvation, and anaerobiosis. In addition, Bott et al beneficially teach that it is possible to identify a range of indicator proteins that are rapidly induced in response to stress, and that these proteins may provide valuable information about the health of the environmental system being studied (see, for example, Abstract, and pg. 124).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Duncan et al based upon the beneficial teachings provided by Larossa et al, with respect to the art-recognized method of using microorganisms to monitor an environmental condition or changes in a condition, and by Bott et al, with respect to the teaching that a plurality of bacterial stress proteins exist and could be used as indicators of an environmental condition, as discussed above. Furthermore, the cited references particularly point out that the level of a protein such as a stress protein or heat-shock protein (i.e., a biochemical composition) can be measured in bacteria that have been exposed to an

environmental condition, such as contamination by toxic compounds, and that it would be beneficial to develop a monitoring technology using relative levels of stress proteins in conjunction with their induction patterns. In addition, the cited references particularly point out that microarrays can be used to determine the amount of RNA or protein a microorganism, such as bacteria, expresses upon exposure to a stressor, such as a change in environmental condition, and therefore, it would have been obvious and beneficial for the skilled artisan to use the methods taught by Duncan et al so as to determine an environmental condition by measuring a biochemical composition of one or more microorganisms. The result-effective adjustment of particular conventional working conditions (e.g., using a particular microorganism, measuring a particular number of biochemical compositions, and/or using a particular method to determine the biochemical composition) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Applicants' arguments concerning the above USC 103 rejection have been carefully considered but are not deemed to be persuasive of error in the rejection. Applicants argue that it is questionable whether determining stress of microorganisms present in activated sludge of a wastewater treatment process can be considered an

"environmental condition." The Examiner respectfully disagrees. The Examiner would like to direct Applicant to the text of the instant specification, page 2, lines 10-29, where "environmental condition" is defined as concerning specific chemicals in the environment. Furthermore, bacteria and other microorganisms produce stress proteins under circumstances when a physical or chemical stressor (i.e., temperature, humidity, lack of water/air, presence of toxic chemicals) induces production of the protein. More than one stressor can occur at once, and therefore, more than one stress protein can be induced at once, which would lead one of ordinary skill in the art to the idea that a plurality of these stress proteins, or biomolecules, can be measured at once. Duncan et al and Bott et al beneficially teach that a plurality of different stress proteins can create a protein fingerprint or protein induction pattern in activated sludge cultures exposed to chemical stressors, indicating the condition of the microorganisms that produced the stress proteins. Duncan et al further teach that it would be beneficial to monitor relative levels of stress proteins and their induction patterns to develop useful monitoring technology based on the microbial stress response.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that no functional relationship needs to exist or to be known between the environmental condition and the plurality of biomolecules that are measured) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda P. Wood whose telephone number is (571) 272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

APW
Examiner
Art Unit 1655

APW

CHRISTOPHER R. TATE
PRIMARY EXAMINER